

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARTHA FRANCINE KAY,
TERESA RITA RATNARAJ, and
PATRICIA LYNN SANDLER

Appeal No. 2001-0980
Application 08/953,146

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 4, 6 through 10, and 12, all the claims pending in the application.

Claim 1 is representative of the subject matter on appeal and reads as follows:

1. An alkanol free anhydrous glycol based oral analgesic composition comprising an analgesia producing amount of benzocaine, a glycol solvent system for the benzocaine in an amount sufficient to dissolve the benzocaine comprising polyethylene glycol, having a molecular weight of about 400 to 600 and a preservative agent in an amount sufficient to protect against microbiological degradation consisting essentially of a combination of about 0.05% to about 0.2% by weight of methylparaben and about 0.25% to about 0.5% by weight of phenylcarbinol each based on the weight of the total composition.

The references relied upon by the examiner are:

Singleton et al. (Singleton)	5,547,657	Aug. 20, 1996
Reuter et al. (Reuter)	5,446,063	Aug. 29, 1995

Di Colo et al.¹ (Di Colo), "A Study of Drug-Vehicle Interactions in Anhydrous Polyethylene Glycol Ointments" Chem. Abstracts, Vol. 99, No. 163959, Sept. 1983

Yamahira², (Sumitomo) "Preservative for interferon formulations." Chem. Abstracts, Vol. 102 No. 32270 Mar. 28, 1993

Remington's Pharmaceutical Sciences, Mack Publishing Co., pg. 1891, 15th edition, 1975

Claims 1 through 4, 6 through 10, and 12 stand rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the examiner relies upon Singleton, Di Colo, Remington, Reuter, and Sumitomo. We reverse.

¹ We have obtained a copy of the full text Di Colo document and have considered the full text document in reaching this decision.

² The document which is the subject of this abstract is a Japanese published examined patent application. We have obtained a copy of that document as well as a translation thereof. Our consideration of the issues raised in this appeal have been based upon the translation.

DISCUSSION

Our consideration of the examiner's position on appeal has been needlessly hampered by the manner in which the examiner drafted the Examiner's Answer. The examiner states at page 3 of the Answer that the prior art rejection is "set forth in prior Office action, Paper No. 5." Turning to Paper no. 5, we find that the claims are rejected "for reasons of record." It is only from a review of the first Office Action (Paper No. 2) that we are able to glean the substance of the examiner's rejection.

The examiner's reference to a multiple Office actions in the Examiner's Answer for a statement of rejection is manifestly improper. As set forth in the Manual of Patent Examining Procedure (MPEP) § 1208 examiners may incorporate in the Answer only those statements of grounds of rejection which appear in a single prior Office action. While ordinarily the examiner's action would necessitate a remand so that a proper Examiner's Answer could be prepared and entered in the file, our review of the case has revealed that the examiner's rejection is without factual support. Under these circumstances, we will not remand the application but proceed to a decision on the merits.

Claim 1 requires, inter alia, the presence of polyethylene glycol having a molecular weight of about 400 to 600. The examiner stated at page 2 of the first Office Action that Singleton teaches a composition which contains polyethylene glycol. While original claim 1 did not require a polyethylene glycol having a particular molecular weight, original claim 5 did. The examiner's first Office action did not account for the molecular weight requirement of claim 5. This mistake on the part of the examiner was

perpetuated when appellants amended claim 1 in response to the first Office action by adding the molecular weight requirement of claim 5. Neither the Final Rejection nor the Examiner's Answer come to grip with this aspect of the claimed invention. This is important since the composition of Singleton contains a polyethylene glycol having a number average molecular weight of 200 to 300. As explained at column 3 lines 13-21 of Singleton, polyethylene glycol 400 and polyethylene glycol 600 do not provide a stable mouth rinse at temperatures approaching 0° C. The examiner has not explained why one of ordinary skill in the art would have found it obvious to use polyethylene glycol having a molecular weight of about 400 to 600 in the composition of Singleton as required by the claims on appeal. Obviousness under 35 U.S.C. § 103(a) must be based upon the subject matter of a claim as a whole. Where as here the examiner's consideration of obviousness under this section of the statute is not based upon the subject matter as a whole, that determination is legally flawed and must be reversed.

There is a second substantive reason why the examiner's rejection must be reversed. At page 2 of the first Office action the examiner states that Sumitomo teaches utilization of both methylparaben and phenylcarbinol (benzyl alcohol) in pharmaceutical compositions. As we understand the examiner's position it is the Sumitomo reference which is relied upon to establish the obviousness of using methylparaben and phenylcarbinol together as a preservative agent in a pharmaceutical composition. Again, we are hampered in our analysis of the examiner's position due to the manner in which it is presented. If this is the examiner's position it is without factual support on this record.

As explained above, the examiner relied upon a Chemical Abstracts citation of Sumitomo. For reasons unclear from the record, the examiner did not obtain a full text copy of the Japanese patent document as well as a translation thereof. Obviousness determinations under 35 U.S.C. § 103 are fact intensive. It is common sense that a full text document will contain more facts than an abstract of the document. Why the examiner would spend the agency's resources as well as those of appellants in pursuing patentability inquiries based upon a less than complete set of facts is not clear. Our review of the translation makes clear that the examiner's conclusions reached from considering the abstract are incorrect.

The Sumitomo invention is directed to a pharmaceutical composition which contains interferon and thimerosal. As explained by Sumitomo, it can be difficult to preserve protein such as interferon since some of the normal preservatives including parabens, phenols, and alcohols have a protein denaturing effect. The Sumitomo document discloses that thimerosal is able to preserve an interferon composition without exerting a negative influence on the stability of the protein.

Sumitomo does discuss the use of methyparaben, propylparaben, and benzyl alcohol as preservatives for interferon. However, in reading the full text translation of the document, it is clear that that discussion is premised upon their use in the alternative, not the conjunctive as urged by the examiner. As explained at page 3 of the translation, an interferon solution was formed having a specified strength to which thimerosal, benzyl alcohol, and a mixture of methyl and propylparaben respectively were added as preservatives. As seen from Table I of the document, four separate interferon compositions were formed and tested. The first had no preservative, the

second contained thimerosal, the third contained benzyl alcohol, and the fourth contained a combination of methylparaben and propylparaben. In reading the full text document, we do not find a teaching or suggestion that benzyl alcohol should be used in combination with methylparaben as required by the claims on appeal.

The decision of the examiner is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

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